

**K040477 MONODERM**May 18, 2004  
84 days to decisionK040477 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k040477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Feb 24, 2004
Decision date	May 18, 2004
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surgical Specialties Corp</b>
Location	Reading, PA, US
Contact	ELIZABETH LAZARO
510(k) history	22 submissions · 22 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040477/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 19, 2026